UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ET AL. EX REL. DR. JESSE POLANSKY,

Plaintiff,

- against -

PFIZER, INC.,

Defendant.

MEMORANDUM DECISION AND ORDER

04 Civ. 0704 (BMC)

COGAN, District Judge.

Before the Court is defendant's motion to dismiss plaintiff's Fifth Amended Complaint in this *qui tam* action under the False Claims Act ("FCA") 31 U.S.C. § 3729 et seq. Plaintiff alleges that Pfizer has engaged in an illegal marketing campaign for its popular statin Lipitor. According to plaintiff, defendant misrepresented the patient populations to whom the drug should be prescribed by encouraging doctors to prescribe Lipitor to lower their patients' cholesterol even when the patients' risk factors for cardiac heart disease and their cholesterol levels failed to indicate that they needed drug intervention according to the National Cholesterol Education Program Guidelines ("NCEP Guidelines" or "Guidelines"). Plaintiff argues that by marketing the drug to patients not within these Guidelines, defendant improperly induced physicians to prescribe the medication, pharmacists to fill the prescriptions, and Medicare and Medicaid to pay for the drug for those patients. Since Medicare and Medicaid do not reimburse

off-label prescriptions,[1] plaintiff contends the claims submitted as a result of defendant's conduct constitute violations of the False Claims Act.

Judge Korman, to whom this case was assigned previously, dismissed the Fourth Amended Complaint with leave to amend. See U.S. ex rel. Polansky v. Pfizer, Inc., No. 04-cv-0704 (ERK), 2009 WL 1456582 (E.D.N.Y. May 22, 2009). Familiarity with Judge Korman's decision dismissing the Fourth Amended Complaint is assumed, and I will therefore not repeat his thorough discussion of the background of plaintiff's claim, the FDCA, 21 U.S.C. §§ 301–97, the False Claims Act, 31 U.S.C. § 3729 *et seq.*, the FDA approval process, and the NCEP Guidelines upon which plaintiff's case wholly relies. Suffice it to say that the FDA requires that drugs be accompanied by FDA approved labels announcing, *inter alia*, adequate directions for use. 21 CFR § 201.5. These directions must indicate the purposes for which the drug has been found to be both safe and effective.

Although Judge Korman's decision was based on plaintiff's failure to plead fraud with particularity under Federal Rule of Civil Procedure 9(b), he was not subtle in raising doubts about plaintiff's theory of liability – doubts which might not be cured by more specific pleading. Nevertheless, he provided plaintiff with the opportunity to address his pleading deficiencies, thus not foreclosing the possibility that plaintiff could potentially state a plausible claim.

Plaintiff may or may not have remedied his Rule 9(b) problem, but the issues to which Judge Korman alluded remain and are, in my view, fatal to the claim. Specifically, in arguing that its label restricts the prescription of Lipitor to patients within the NCEP Guideline range, plaintiff has attempted to turn an advisory snippet into a prohibitory mandate – one that would

[1] Reimbursement under Medicaid is substantially limited to "covered outpatient drugs" which do not include drugs "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396b(i)(10). A medically accepted indication includes uses which are "approved under the Federal Food Drug and Cosmetic Act" or which are included in specified drug compendia. Id.

relieve government insurers of the obligation to pay for drugs that doctors believe certain of their patients need, and that the patients themselves want, in order to improve their health.

This case has been pending so long that two labels are now at issue: one approved in 2005 and a second approved in 2009. The only difference between the labels relevant to this case is the omission of a NCEP Guidelines chart from the 2009 label. Both sides agree that the 2009 revisions did not effect a substantive change in the labeling of Lipitor, but Pfizer contends that the 2009 revision substantiates its argument that the NCEP Guidelines have always played a limited role in the context of the label.

To fully understand the labels, it is necessary to examine them in their totality and to appreciate their underlying purpose. It should first be noted that only people immersed in the pharmaceutical industry would refer to this document as a "label." This is not the piece of paper affixed to the outside of a pill bottle, or one of the accordion-style informational attachments a pharmacist attaches to the pill canister when he fills the prescription.[2] The 2009 label, for example, which is the shorter of the two, has over twenty single-spaced pages of small font – approximately the same length as Thomas Paine's *Common Sense*. Indeed, outside of the pharmaceutical industry, it would more properly be characterized as a pamphlet or a brochure. Among a wealth of other information, it describes the drug's chemical structure, its active mechanism, its "pharmacodynamics," "pharmacokinetics," and the results of various clinical studies. Although a consumer (who probably never sees it) might be able to understand parts of the label, much if not most of the document is only within the ken of a doctor, pharmacist, or biochemist.

[2] See 21 CFR 321(m) defining labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." See also U.S. v. Kordel, 335 U.S. 345 (1948), noting that the word "accompanying" has a broad meaning.

As Judge Korman noted, the case turns on the effect of the information in the recommended NCEP Guidelines. These Guidelines appeared in the "Indications and Usage" section of the 2005 label but do not appear in the 2009 label. In the 2005 label, the NCEP Guidelines appeared as follows:

TABLE 6. NCEP Treatment Guidelines: LDL-C Goals and Cutpoints for Therapeutic Lifestyle Changes and Drug Therapy in Different Risk Categories

Risk Category	LDL-C Goal (mg/dL)	LDL Level at Which to Initiate Therapeutic Lifestyle Changes (mg/dL)	LDL Level at Which to Consider Drug Therapy (mg/dL)
CHD [a] or CHD risk equivalents (10-year risk >20%)	<100	≥100	≥130 (100-129: drug optional) [b]
2+ Risk Factors (10-year risk ≤20%)	<130	≥130	10-year risk 10%-20%: ≥130 10-year risk <10%: ≥ 160
0-1 Risk factor [c]	<160	≥160	≥190 (160-189: LDL-lowering drug optional)

[a] CHD, coronary heart disease
[b] Some authorities recommend use of LDL-lowering drugs in this category if an LDL-C level of < 100 mg/dL cannot be achieved by therapeutic lifestyle changes. Others prefer use of drugs that primarily modify triglycerides and HDL-C, e.g., nicotinic acid or fibrate. Clinical judgement also may call for deferring drug therapy in this subcategory.
[c] Almost all people with 0-1 risk factor have 10-year risk <10%; thus, 10-year risk assessment in people with 0-1 risk factor is not necessary.

Simply stated, plaintiff contends that this portion of the 2005 label restricted Pfizer from marketing the drug to doctors to be used on patients whose risk profiles fell outside the parameters indicated by the NCEP Guidelines. Plaintiff recognizes that nothing in the law limited doctors from prescribing Lipitor to patients outside of the Guidelines. The restriction, according to plaintiff, is that Pfizer could not suggest to a doctor that he prescribe the drug for patients outside the Guidelines. Thus, if a Pfizer representative told a doctor that he should prescribe Lipitor to any of his patients who smoke and have a bad family cardiac history (i.e., two risk factors) and LDL levels of 131 mg/dL or more, that advice would be proper because that patient falls within the Guideline range. However, change the number in the sales pitch to 125 mg/dL, or even 129mg/dL, and any prescription issued by a doctor who relied on that advice,

and which Medicare or Medicaid subsequently reimbursed, would constitute a false claim. Of course, plaintiff's alleged "false statements" are not as *de minimis* as this illustration, but there is no logical place to draw a line on plaintiff's theory. According to plaintiff, any marketing of the drug for patients outside the Guidelines' range is "off-label marketing," resulting in the filing of false claims under the False Claims Act.

I reject this drastically elongated reach of the False Claims Act for a number of reasons. First, the plain meaning of the word "Guideline" is one of counseling and advice, not mandatory limitation. That is, the Guidelines "guide," they do not mandate. I have reviewed numerous dictionaries trying to find a definition of "guidelines" with a mandatory connotation, and although one may exist somewhere, the ones that I have found provide that "guidelines" are by definition advisory. For example, the definition found at BuisnessDictionary.com defines "guideline" as "Recommended practice that allows some discretion or leeway in its interpretation, implementation, or use." Guideline Definition, Dictionary.com, http://www.businessdictionary.com/definition/guideline.html (last visited Oct. 9, 2012). Other dictionaries may not stress discretion to the same extent, but they do make the merely advisory nature of the word apparent.[3]

The United States Sentencing Guidelines promulgated by the Congressionally-created United States Sentencing Commission are an interesting definitional analogue. As is well known, the Commission's pronouncements were required to be applied as "mandatory guidelines" at the time they were enacted until the decision in United States v. Booker, 543 U.S.

[3] See e.g. Mellinkoff's Dictionary of American Legal Usage (1992) defines "guidelines" as "more or less brief statements of policy . . . presumed to be for general guidance, as distinguished from detailed compliance." Merriam-Webster's Collegiate Dictionary Tenth Edition (1994) defines "guideline" as "an indication or outline of policy or conduct," while the Oxford Dictionary online defines "guideline" as "a general rule, principle, or piece of advice." Guideline Definition, englishoxforddictionaries.com, http://english.oxforddictionaries.com/definition/guideline?region=us (last visited Oct. 9, 2012).

220 (2005). Yet many commentators have noted the Orwellian nature of the title that the Commission placed upon those pronouncements; i.e., that the very idea of "mandatory guidelines" was a contradiction in terms, adopted to obscure or appear to soften the unprecedented intrusion into sentencing judges' discretion. See M. Torrey, The U.S. Sentencing Commission's Best Response to Booker is to Do Nothing, 24 Fed. Sent. R. 387, 388, 2012 WL 3552913 (2012) ("'Mandatory guidelines,' an oxymoron, was not a term of art in the early 1980s and . . . did not become one until the Commission coined it."); J. Fallows and G. Hall, The Injustice of Sentencing Guidelines, The Atlantic (Mar. 23 2011, 3:08 PM) http://www.theatlantic.com/national/print/2011/03/the-injustice-of-sentencing-guidelines, (referring to the "mandatory guidelines" as "an oxymoron if I ever heard one"); S.G. Thompson, The Booker Project: The Future of Federal Sentencing, 43 Hous. L. Rev. 269, 269 (2006) ("the oxymoron" of mandatory guidelines "was not lost on most observers"); J. H. McCall, Jr., The Emperor's New Clothes: Due Process Considerations under the Federal Sentencing Guidelines, 60 Tenn. L. Rev. 467, 523 (1993) ("the [proposed alternatives to the mandatory guidelines] may serve to take the oxymoron out of 'guidelines' . . .").

Everything about the two labels at issue in this case suggests that the NCEP Guidelines, as a matter plain language, fall well within the usual, non-compulsory definition of the word guidelines. Let us look first at the 2009 label, because that is where plaintiff's claim is most obviously strained. The Guidelines Chart set forth above, and upon which plaintiff's entire case depends, nowhere appears in the label. A person reading the "Indications and Usage" section of the 2009 label must come away with one clear meaning: the drug is to be used if a physician believes his patient should lower his cholesterol. That is the drug's essential purpose as defined by the label – to lower cholesterol. And as long as Pfizer markets the drug to lower cholesterol,

it is doing what the label permits. Notably, the 2009 label does include a guideline range for patients between the ages of ten and seventeen – making the absence of similar guidelines for adults more conspicuous.

As defendant notes, it is of some significance that although almost the entirety of defendant's motion was directed to this change in the 2009 label, plaintiff does not refer to it until page fifty-four of his opposing memorandum. Even then, his response is meager: plaintiff simply notes that the NCEP Guidelines are still referenced in the 2009 label. But the location and brevity of that reference does plaintiff's theory more harm than good. Under the section of the 2009 label titled "Dosage and Administration" – that is, how much to prescribe and how to give it, not to whom – the new label provides that "the starting dose and maintenance doses of Lipitor should be individualized according to patient characteristics such as goal of therapy and response."[4] There is nothing restrictive in that sentence. Instead, plaintiff bases his whole case on a four-word parenthetical at the end of that sentence: "(see current NCEP Guidelines)." According to plaintiff, this brief citation imposes the same restrictions as he contends were imposed by actually displaying the NECP chart on the 2005 label.

I see it as just the opposite: that is, the 2009 label demonstrates the advisory, non-confining nature of the 2005 label's inclusion of the NCEP chart. First, dealing with that parenthetical in the 2009 label alone, it defies reason to believe that the FDA, well aware that physicians regularly prescribe Lipitor for patients outside of the Guidelines, would relegate these important and mandatory (in plaintiff's view) restrictions to something that a doctor must search for elsewhere – not to mention that the label does not even tell the doctor where to find the

[4] Although the label mentions dosage limits for patients taking certain other medications, whether the drug should be prescribed is generally a question of clinical judgment.

Guidelines. It's like a citation in a brief to a reported decision which contains no information as to where the decision is reported.

It is not as though the 2009 label could not bear the weight of the deleted chart, or at least a website citation. As noted, the label is over twenty pages long, so including this crucial (in plaintiff's view) information would not have added much to its verbosity. The fleeting reference to the NCEP Guidelines is particularly telling since obviously the FDA not only knew that doctors were widely prescribing Lipitor for patients outside the Guidelines when it approved this revised label, but it also must have known about the pendency of this lawsuit.

Moreover, plaintiff's argument ignores the fact that the "Indications and Usage" portion of the 2009 label contains a section clearly titled: "Limitations of Use" – a perfect place to have inserted any prohibitory language had the FDA desired to do so. (There are several other places that would serve equally well.) But there is no reference to the NCEP Guidelines in that section at all. In fact, there are no limitations as to the appropriate patient population offered in that section – just a note indicating that it is unclear whether Lipitor works for two specific classes of patients with certain types of high cholesterol. Even there, whether to prescribe Lipitor to those patients is left to the doctor's judgment.

Plaintiff therefore has no claim under the 2009 label because it does not limit its use to patients within the Guidelines. This might leave plaintiff with a claim for prescriptions written under the 2005 label. As to that, it might be enough to dispose of this argument to note that plaintiff concedes that no substantive change was effected by the 2009 label, so if plaintiff's claim fails under the latest label, it must fail under the earlier one as well. This is a concession plaintiff had to make, as the stated objective of the 2009 revisions was to "enhance the ability of health care practitioners" to effectively "discern the most critical information," not to make a

substantive change. In this regard, it is noteworthy that the FDA did not consider the NCEP Guidelines chart to consist of sufficiently "critical information" to include in the 2009 label, which of course is an indication of its permissive nature in the 2005 label as well.

But the non-substantive change between the 2005 and 2009 label is not the only indicator that adherence to the Guidelines was not a marketing restriction. It is apparent from the 2005 label itself. The advisory, rather than mandatory, application of the NCEP chart is made plain by one of its footnotes:

> Some authorities recommend use of LDL-lowering drugs in this category if an LDL-C level of <100 mg/dL cannot be achieved by therapeutic lifestyle changes. Others prefer use of drugs that primarily modify triglycerides and HDL-C, e.g., nicotine acid or fibrate. Clinical judgement [sic] also may call for deferring drug therapy in this category.

The full text of the Guidelines, not included on the Lipitor label, also makes the advisory nature of the Guidelines clear as it notes that the report "should not be viewed as a standard of practice" but that the Guidelines "represent general guidance that can assist in shaping clinical decisions" and "should not override a clinician's considered judgment in the management of individuals."[5] Once the doctor's clinical judgment is introduced as the determinative factor in the decision making process, it must be apparent that this data serves as a recommendation, not a limitation or prohibition. I cannot accept plaintiff's theory that what the scientists at the National Cholesterol Education Program clearly intended to be advisory guidance is transformed into a legal restriction simply because the FDA has determined to pass along that advice through the label.

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[5] National Cholesterol Education Program, Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) (September 2002), available at http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf, at I-2.

Another consideration driving my conclusion is the ease with which the FDA could have limited reimbursable prescriptions of Lipitor to patients within the Guidelines had it wanted to do so. For example, it could have easily required Pfizer to simply add to the label: "This drug is not approved for, and should not be prescribed to, any patient who falls outside of the NCEP Guidelines."[6] If that or similar language appeared on the label, then virtually any effort by Pfizer to market to doctors for their patients outside of the Guidelines would have to be considered off-label marketing. But there is no such restriction. Nor is there any such prohibition in the label's "Contraindications" section, which only proscribes administering the drug to pregnant or breastfeeding women.

There can be no question that the FDA commonly requires such restrictive language in labeling. For example, the label of GlaxoSmithKline's ("GSK") anti-migraine drug Imitrex contains the admonition, under its "Indications and Usage" section, "IMITREX Tablets are indicated for the acute treatment of migraine attacks with or without aura in adults. IMITREX Tablets are not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine." See, Imitrex Prescribing Information, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020132s024s026lbl.pdf (last visited Nov. 8, 2012). Again, it seems clear that if GSK marketed Imitrex for migraine prevention, rather than treatment, it would be marketing the drug for an off-label use. Similarly, in U.S. ex rel. Carpenter v. Abbot Laboratories, Inc., 723 F. Supp.2d 396, 398 (D. Mass. 2010), the approved label included the admonition that "once-daily administration of Kaletra is not recommended in therapy-experienced patients" (emphasis omitted), and the pharmaceutical

[6] Cf. 21 C.F.R. Part 530 (FDA rule prohibiting cephalosporin, an antibiotic, from being used for specifically identified purposes and conditions).

company defendant was accused of marketing Kaletra to doctors for therapy-experienced patients. That is clearly an off-label marketing campaign, and stands in contrast to plaintiff's accusation against Pfizer in this case.

Since no such restriction exists here, the advisory NCEP chart by itself cannot support the conclusion that Pfizer is doing anything "false" or is aiding in the submission of "false claims" when it markets the drug as effective to patients who fall outside of the Guideline parameters. It is marketing the drug, after all, for an FDA sanctioned purpose – to lower cholesterol, not to promote hair growth or cure cancer.

This is not to say that every limitation on the use of a particular drug must be expressly set forth in the label, or that only marketing directed to an expressly proscribed use is actionable under the False Claims Act. I recognize that off-label marketing includes marketing for any use that the FDA has not specifically approved. And there are, of course, some potential uses of any drug that are so obviously removed from its stated purpose that marketing to those uses would be clearly be off-label (like the hair growth or anti-cancer therapy I postulated above). But before a company can be deemed to have engaged in fraudulent conduct – more than fraudulent, actually quasi-criminal conduct under the False Claims Act – a plaintiff ought to have something more compelling than plaintiff has argued here.

There is a distinction between off-label marketing to achieve a treatment not contemplated by the label (e.g., hair growth or curing cancer), and marketing to a patient population not specifically mandated by the label. If the drug does what it is supposed to do, then it is not too much to ask for a label that more specifically limit that use to a particular population, if that is what the FDA deems to be appropriate. The labels at issue here indicate that the FDA has specifically approved Lipitor to lower cholesterol, but it has not restricted or

even recommended against its use for any particular patient population except those with active liver disease, demonstrated hypersensitivity to the drug, and pregnant women and nursing mothers. Plaintiff does not accuse Pfizer of marketing to those populations.

Not only has the Food and Drug Administration not prohibited doctors from prescribing Lipitor to lower cholesterol in patients who fall outside the NCEP Guidelines, but government Medicare and state Medicaid providers have not passed any regulations restricting reimbursement when a doctor, in his professional judgment, determines that his patient would benefit from statin therapy to lower cholesterol. If the FDA or the public insurers want to outlaw Lipitor for patients falling outside of the NCEP guidelines, they have the power to do it, both legally and practically, and could do it expressly. They have chosen not to – very possibly to avoid the negative reaction that the public would likely have if a patient's doctor decided that the patient should use a statin to lower his cholesterol, but then had to tell the patient that the patient was going to have to pay for the drug himself because public insurers refused to cover it. If Government regulatory and benefits agencies are going to interfere to that extent with the physician-patient relationship, those agencies should come out and do it expressly, and overcome any political consequences that might flow from such a decision.

The False Claims Act, even in its broadest application, was never intended to be used as a back-door regulatory regime to restrict practices that the relevant federal and state agencies have chosen not to prohibit through their regulatory authority. Furthermore, there are protections required for the implementation of prohibitory regulations (for example, the right to public comment or administrative challenge), which the False Claims Act cannot be used to circumvent.

Defendant puts its best: Off-guideline does not equate to off-label. Having determined that the NCEP Guidelines in the 2005 label, and the passing reference to them in the 2009 label,

were merely informational and advisory rather than restrictive limitations, I hold that defendant has not engaged in off-label marketing, and has therefore not violated the FCA.

CONCLUSION

Since I have found that defendant has not engaged in off-label marketing of Lipitor according to plaintiff's allegations, I need not reach defendant's remaining arguments. Its motion to dismiss is therefore granted. The Clerk is directed to enter judgment in favor of defendant, dismissing the complaint.

SO ORDERED.

s/ BMC

U.S.D.J.

Dated: Brooklyn, New York
November 14, 2012